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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/957,046	10/24/97	DALUGE S	PB1517US3

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EXAMINER	
BERCH, M	
ART UNIT	**PAPER NUMBER**
1611	13

DATE MAILED: 09/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/957,045	Applicant(s) Daluge
	Examiner Mark L. Berch	Group Art Unit 1611

☒ Responsive to communication(s) filed on *Aug 2, 1999* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *9 and 18-22* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *9 and 18-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. There still remains previous point 1. Applicants' traverse on this point is unpersuasive. Applicants state, "For example, amines such as 1-aminoribose are excluded." This is not understood. The question here is the definition of a moiety R^3, which cannot be 1-aminoribose because that is a molecule, not a moiety. In fact, amino groups aren't even mentioned in the definition of R^3. The essential problem remains: There is no such thing as a "Glycosidic bond". There are a single, double, triple, dative, and normalized bonds, etc. If would be helpful if applicants actually drew what a Glycosidic bond looks like. For example, while the bond goes from the N-9 of the purine, the examiner does not even know whether the Glycosidic bond goes to a N, O or C. Is it in the category of a covalent or ionic bond?

2. The phrase, "an acyclic group, wherein the carbon atoms may be substituted by one or more heteroatoms" is redundant. An acyclic group by its very nature could already have heteroatoms; acyclic only requires that there be no rings present. Thus, e.g. C(O)H is an acyclic group. The same is true of all the substituents listed e.g. halogen. "Acyclic group" already provides for Halogen substituents.

3. There still remains previous point 3. If that is what is intended then a) applicants must put that language into the claims, and b) applicants must show that one of ordinary skill in the art reading this specification would understand that this is what was intended. Ordinarily, the term refers to something of the type RP(O)(OH), which leaves open the question of what R is.

4. There still remains previous point 4. Page 10 does not state what the number or nature of the heteroatoms are. At least one must be N, S, or O, but could a second be replaced with Se or P? How many could there be?

5. Ambiguity about the use of the tem "group" remains. The question here is whether the "group" (to which optional substituent may be attached) must be entirely what the preceding adjective (carbocyclic or acyclic, respectively) requires, or just partially. Thus, a group like benzyl has an acyclic component (the CH_2) and a cyclic component (the benzene ring). But it is not entirely acyclic or carbocyclic. The term "group" is not clear as to whether such a mixed group is included. Is 4-(1-piperidinyl) phenyl permitted? Piperidinyl is not permitted as a substituent on the carbocyclic, so the question is, does a phenyl which is substituted by a heterocycle qualify as a

heterocyclic group? Does "heterocyclic group" require that it be entirely (optionally substituted) heterocycle?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daluge '697 in view of Vince or Daluge '671, further in view of Norbeck, Vince, Bothwick or Shealy.

The reasons were given previously; the traverse on this point is unpersuasive. Applicants make a lot of assertions without presenting evidence. For example, the Shealy process, which is there simply to show that it is known to use aqueous acid, has "contaminant which render this process unsuitable for large scale manufacture and formulation." But there is no evidence for this assertion. More specifically, the crucial issue is that of removing the N-2 protecting group early (as is done by applicant) verses later as is done by Daluge. But this argument requires a showing that removal at the earlier stage unexpectedly gave fewer problems on deprotection than removal at a later stage. Instead, applicants merely assert (paragraph bridging pages 6-7 of the remarks) that this is so, without actually showing it. Whatever loses which occur when the N-2 protecting group is removed in the later stage as is done by

Daluge must be balanced against the losses that occur when applicants remove their protecting group at the earlier stage. Applicants must actually show that this problem exists, not merely assume it.

Claim 9, 18-20 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 413,544 in view of newly cited Norbeck, Vince, Bothwick or Shealy.

The reasons were given previously; the traverse on this point is not entirely understood. It is clear that an impasse has been reached on this issue. The argument here is whether (II) of the prior art falls within the VI of the claims. The examiner simply does not understand why it does not. Applicants say, "R^3 cannot be unstable amines as described above." What does this mean? R^3 is not an amine, it is a substituent which is attached to an amino group. Note the lower right of VI. Thus, the question is, does the definition of R^3 in the claims embrace the $O(CH_2)_3OR_5$ of the prior art. Why doesn't it? To begin with, R^3 can be an "acyclic group". The $O(CH_2)_3OR_5$ is an acyclic group. Next applicants point out that the reference does not use aqueous acid. That is why there are secondary references. The reference is not asserted to be an anticipation, only that it renders the claims obvious. With regard to better yields, etc, applicants must present a side by side comparison using the same substituent. Applicants point to example 8 of their application, but that does not use the same substituent as is seen in the prior art.

Claims 9, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norbeck, Vince, Bothwick or Shealy, in view of EP 413,544 or Daluge '697.

The reasons were given previously; the traverse on this point is unpersuasive. Largely the same issues arise here. The secondary references do not have to teach"benefits of making the claimed modification", only render it obvious. Both EP 413,544 and Daluge '697 do exactly that.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718.

Mark L. Berch

Primary Examiner

Group 1610 - Art Unit 1611

September 10, 1999